Enforcement Report - Week of February 20, 2019

Class I Drugs Event

Event ID:
81441

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
10/26/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/11/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide

Associated Products

Product Description:
Levetiracetam in 0.54 % Sodium Chloride Injection 1,500/mg/100mL (15mg/mL), For intravenous Infusion Only, 1 x 100 mL Infusion bag, Manufactured by: Gland Pharma Limited Hyderabad - 500 043, India Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540 UPC 343598637525 ---- NDC 43598-637-52

Product Quantity:
2770 bags; 277 selling units

Reason for Recall:
Labeling: Label Error on Declared Strength; the pre-printed text on the primary infusion bag and the NDC incorrectly identifies the product as Levetiracetam in 0.75% Sodium Chloride (1000 mg/100 mL) however, the external foil pouch correctly identifies the product as Levetiracetam in 0.54% Sodium Chloride Injection (1,500/100 mL).

Recall Number:
D-0485-2019

Code Information:
ABD807, exp 05/2020

Class II Drugs Event

Event ID:
81790

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/18/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/11/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
LGM Pharma LLC
2758 Circleport Dr
Erlanger KY United States

Distribution Pattern:
Distributed to MS and Spain

Associated Products

Product Description:
CIDOFOVIR DIHYDRATE, (Non-Sterile, For Manufacturing Use), 10g, Rx only, ALP PHARM BEIJING CO., LTD, 12-2-620, Jia 69, Fushi Rd., Haidian, Beijing 100049, China. Batch Number JD-BP-37-20150801

Product Quantity:
205 grams

Reason for Recall:
CGMP Deviations: Active Pharmaceutical Ingredient (API) manufacturer is on FDA Import Alert.

Recall Number:
D-0486-2019

Code Information:
Lot number: JD-BP-37-20150801

Class II Drugs Event

Event ID:
81810

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/17/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/08/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Promise Pharmacy, LLC
31818 Us Highway 19 N
Palm Harbor FL United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
Acetylcysteine Ophthalmic Solution, 100mg/ml, 10%, Rx only, Promise Pharmacy Compounding Specialist, 31818 US Hwy 19N, Palm Harbor FL 34684.

Product Quantity:
75 10 ml bottles

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0431-2019

Code Information:
Lot: 11072018@10 BUD: 12/22/2018

Product Description:
Prednisolone and Moxifloxacin Ophthalmic Solution 1%/0.5%, Combo Drops 3 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
43 3 mL bottles

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0432-2019

Code Information:
Lot: 10252018@8 BUD: 2/10/2019

Product Description:
Prednisolone and Gatifloxacin Ophthalmic Solution 1%/0.5%, Combo Drops 3 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
55 3 ml bottles

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0433-2019

Code Information:
Lot: 11052018@4 BUD: 1/18/2019

Product Description:
Prednisolone and Gatifloxacin and Ketorolac Ophthalmic Solution 1%/0.5%/0.5%, Combo Drops: 3 mL Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor FL 34684

Product Quantity:
250 3 ml bottles

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0434-2019

Code Information:
Lots: 09262018@5 BUD: 1/15/2019; 10092018@1 BUD: 1/25/2019; 11052018@1 BUD: 2/21/2019

Product Description:
Prednisolone and Gatifloxacin and Bromfenac Ophthalmic Solution, 1%/0.5%/0.09%, Combo Drops 6 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor FL 34684

Product Quantity:
2057 6 ml bottles

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0435-2019

Code Information:
Lots: 09192018@4 BUD: 12/18/2018; 10112018@1 BUD: 12/24/2018; 10262018@1 BUD: 1/8/2019; 10302018@1 BUD: 1/12/2019; 11082018@6 BUD: 1/21/2019

Product Description:
Prednisolone and Gatifloxacin and Bromfenac, Ophthalmic Solution, 1%/0.5%/0.09%, Combo Drops 3 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor FL 34684

Product Quantity:
900 3 ml bottles

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0436-2019

Code Information:
Lots: 11012018@1 BUD: 1/14/2019; 11022018@1 BUD: 1/15/2019

Product Description:
Prednisolone and Bromfenac Ophthalmic Solution, 1%/0.09% Combo Drops 3 mL, Rx Only, Compounded Prescription, Promise Pharmacy 31818 US Hwy 19N, Palm Harbor FL 34684

Product Quantity:
167 3 ml bottles

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0437-2019

Code Information:
Lots: 09262018@6 BUD: 12/25/2018; 11052018@2 BUD: 2/3/2019

Product Description:
Vitamin B Complex, Dexpanthenol/Leucine/Niacinamide/Pyridoxine/Riboflavin/Thiamine 2 mg/2.5 mg/25 mg/ 25 mg/ 2 mg/ 25 mg/mL 10 mL vial, Rx Only, Compounded Prescription, Promise Pharmacy Compounding Specialists, 31818 US Hwy 19N, Palm Harbor FL 34684

Product Quantity:
204 10 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0438-2019

Code Information:
Lots: 10092018@4 BUD: 1/7/2019; 11122018@7 BUD: 2/10/2019

Product Description:
Multi Trace, Zinc/Copper/Manganese/Selenium 5mg/1mg/0.5mg/60mcg/ml, injection 30 mL, Rx Only, Compounded Prescription, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
3 30 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0439-2019

Code Information:
Lot: 10312018@5 BUD: 12/15/2018

Product Description:
Vitamin D3 50,000iu/mL, injection 5 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
210 5 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0440-2019

Code Information:
Lots: 09112018@10 BUD: 1/2/2019; 09212018@9 BUD: 1/12/2019; 11132018@10 BUD: 2/27/2019

Product Description:
Trim Complete, Methlonine/Inositol/Choline/Thiamine/Riboflavin/Niacinamide Dexpanthenol/Pyridoxine/Methylcobalamin/Leucine/Chromium 25 mg/50 mg/50 mg/25 mg/2.5 mg/25 mg/2 mg/25 mg/0.5 mg2.5 mg/1.33 mcg/mL injection 10 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
158 10 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0441-2019

Code Information:
Lot: 10022018@6 BUD: 12/31/2018

Product Description:
Methylcobalamin lyophilized 50,000 mcg Injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
252 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0442-2019

Code Information:
Lots: 08212018@11 BUD: 12/19/2018; 10012018@1 BUD: 1/29/2019

Product Description:
Methylcobalamin lyophilized, 10,000 mcg Injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
704 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0443-2019

Code Information:
Lots: 08032018@3 BUD: 01/30/2019; 08272018@6 BUD: 2/23/2019; 09142018@4 BUD: 3/13/2019; 10012018@3 BUD: 3/30/2019

Product Description:
Amino Blend Injection, Ornithine/Arginine/Lysine/Lidocaine 75 mg/75 mg/75 mg/10 mg/mL 10 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
158 10 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0444-2019

Code Information:
Lots: 08302018@12 BUD: 12/24/2018; 10242018@2 BUD: 2/17/2019

Product Description:
Glutathione Injection, 200 mg/mL, 10 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
288 10 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0445-2019

Code Information:
Lots: 09172018@7 BUD: 12/16/2018; 10292018@2 BUD: 1/27/2019

Product Description:
Ascorbic Acid, Compounded-Tapioca, 450 mg/mL Injection, 50 mL, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
196 50 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0446-2019

Code Information:
Lots: 10152018@1 BUD: 1/13/2019; 10312018@2 BUD: 1/29/2019

Product Description:
Thymosin Beta-4, 15 mg Injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
94 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0447-2019

Code Information:
Lots: 08302018@8 BUD: 2/26/2019; 10012018@2 BUD: 3/30/2019; 07052018@2 BUD: 01/01/2019

Product Description:
Sermorelin Theanine/GHRP2, 15 mg/75 mg/5.4 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
25 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0448-2019

Code Information:
Lot: 07202018@4 BUD: 1/16/2019

Product Description:
Sermorelin 9 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
255 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0449-2019

Code Information:
Lots: 06182018@2 BUD: 12/15/2018; 08212018@12 BUD: 2/17/2019; 09212018@15 BUD: 3/20/2019; 11132018@1 BUD: 5/12/2019

Product Description:
Sermorelin/GHRP2/GHRP6, 9 mg/9 mg/9 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
341 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0450-2019

Code Information:
Lots: 07102018@3 BUD: 1/6/2019 08302018@9 BUD: 2/26/2019

Product Description:
Sermorelin/GHRP2/GHRP6 6mg/3mg/3mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
296 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0451-2019

Code Information:
Lots: 08302018@13 BUD: 2/26/2019; 09212018@14 BUD: 3/20/2019

Product Description:
Ipamorelin+Modified GRF 1-29, 9 mg/5mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
927 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0452-2019

Code Information:
Lots: 07052018@1 BUD: 1/1/2019; 09182018@6 BUD: 3/1/2019; 09212018@10 BUD: 3/4/2019; 10052018@1 BUD: 3/18/2019; 11062018@2 BUD: 4/19/2019

Product Description:
Ipamorelin, 9 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
416 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0453-2019

Code Information:
Lots: 07132018@5 BUD: 1/9/2019; 07302018@32 BUD: 1/26/2019; 09182018@7 BUD: 3/17/2019; 10192018@2 BUD: 4/17/2019

Product Description:
Ipamorelin+Sermorelin, 15mg/15mg, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
139 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0454-2019

Code Information:
09212018@12 BUD: 12/20/2018; 11062018@3 BUD: 6/4/2019

Product Description:
Ipamorelin, 15mg, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
93 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0455-2019

Code Information:
Lots: 09182018@4 BUD: 3/17/2019; 10052018@3 BUD: 4/3/2019; 11132018@3 BUD: 5/12/2019

Product Description:
IGF-1 LR3, 620 mcg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
59 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0456-2019

Code Information:
Lot: 06282018@3 BUD: 12/25/2018

Product Description:
Epithalon, 15mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
30 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0457-2019

Code Information:
Lots: 09212018@11 BUD: 12/20/2018; 11132018@4 BUD: 2/11/2019

Product Description:
Bremelanotide (PT 141), 20mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
64 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0458-2019

Code Information:
Lots: 10192018@4 BUD: 12/18/2019; 11132018@5 BUD: 1/12/2019

Product Description:
BPC 157, 10mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
37 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0459-2019

Code Information:
Lot: 11062018@5 BUD: 2/4/2019

Product Description:
HCG, Human chorionic gonadotropin 11,000 units, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
654 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0460-2019

Code Information:
Lots: 06182018@5 BUD: 12/15/2018; 07102018@5 BUD: 1/6/2018; 08212018@8 BUD: 2/17/2019

Product Description:
HCG, Human chorionic gonadotropin 5,000 units, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
2595 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0461-2019

Code Information:
Lots: 06252018@1 BUD: 12/22/2018; 07132018@7 BUD: 1/9/2019; 07262018@2 BUD: 1/22/2019; 08212018@7 BUD: 2/17/2019; 08272018@2 BUD: 2/23/2019; 09052018@2 BUD: 2/28/2019

Product Description:
HCG, Human chorionic gonadotropin 2,000 units, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
819 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0462-2019

Code Information:
Lots: 07172018@15 BUD: 1/13/2019; 08272018@3 BUD: 2/23/2019

Product Description:
Sermorelin, 15mg, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
266 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0463-2019

Code Information:
Lots: 07102018@4 BUD: 1/6/2019; 09142018@6 BUD: 3/13/2019; 10052018@4 BUD: 4/3/2019; 11062018@1 BUD: 5/5/2019

Product Description:
IGF-1-LR3, 3 mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
59 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0464-2019

Code Information:
Lot: 06282018@2 BUD: 12/25/2018

Product Description:
Melanotan II, 10mg injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
43 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0465-2019

Code Information:
Lots: 07202018@3 BUD: 1/13/2019; 09212018@13 BUD: 2/28/2019

Product Description:
ICB-Complex, injection,Inositol/Choline/B1/B2/B3/B5/B6/B12/Leucine/Carnitine/Chromium/Lidocaine: 25mg/25mg/5mg/2.5mg/25mg/5mg/5mg/0.1mg/1.5mg/25mg/25mg/10mg/ML, 10ml, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
846 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0466-2019

Code Information:
Lots: 09262018@1 BUD: 12/25/2018; 10232018@5 BUD: 1/21/2019; 11012018@3 BUD: 1/30/2019

Product Description:
MIC B12+L-Carnitine+Chromium injection, Methionine Inositol Choline Methylcobalamin+L-Carnitine+Chromium, 25mg/50mg/50mg/1mg/100mg/0.4mcg/ml, 10mL, injection, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
64 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0467-2019

Code Information:
Lot: 10102018@1 BUD: 1/8/2019

Product Description:
Nicotinamide Adenine Dinucleotide, 0.5 mg, injection, 10mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
5 10 mL vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0468-2019

Code Information:
Lots: 11062018@13 BUD: 12/21/2018; 11072018@24 BUD: 12/22/2018

Product Description:
Niacinamide injection, 100mg/mL, 5mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
1 vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0469-2019

Code Information:
Lot: 11022018@9 BUD: 12/17/2018

Product Description:
Myer's Cocktail, Pyridoxine/Dexpanthenol/Calcium Gluconate/Niacinamide/Vit B6/Vit B1/Leucine/Vit B5/Riboflavin/Ascorbic

Acid/Hydroxycobalamin/Magnesium Chloride, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
5 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0470-2019

Code Information:
Lot: 11072018@2 BUD: 12/14/2018

Product Description:
Zinc Sulfate, 5mg/mL injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
2 10 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0471-2019

Code Information:
Lots: 11132018@9 BUD: 12/28/2018;

Product Description:
Folic Acid, Injection, 10 mg/mL, 10mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
5 10ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0472-2019

Code Information:
Lots: 11022018@4 BUD: 12/17/2018;

Product Description:
Trim Calm, GABA/Magnesium/Taurine/Theanine, 50mg/50mg/50mg/50mg/ml, 10mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
7 10 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0473-2019

Code Information:
Lot: 11052018@7 BUD: 12/20/2018

Product Description:
Procaine HCl, 2% injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
11 10ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0474-2019

Code Information:
Lots: 11082018@4 BUD: 12/23/2018; 10302018@4 BUD: 12/14/2018

Product Description:
Pyridoxine HCl, 100 mg/mL Injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
8 10ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0475-2019

Code Information:
Lot: 10302018@3 BUD: 12/14/2018

Product Description:
Leucine/Isoleucine/Valine injection, 10mg/10mg/5mg/mL/mL, 10mL vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
15 10ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0476-2019

Code Information:
Lot: 10312018@3 BUD: 12/15/2018

Product Description:
Lysine HCl, 100 mg/mL injection, 10ml, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
11 10 ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0477-2019

Code Information:
Lot: 11132018@8 BUD: 12/28/2018

Product Description:
Dexpanthenol, 250mg/mL Injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
7 vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0478-2019

Code Information:
Lot: 11052018@5 BUD: 12/20/2018

Product Description:
Glycyrrhizic Acid, 8mg/mL Injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
2 10ml vials

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0479-2019

Code Information:
Lot: 11052018@6 BUD: 12/20/2018

Product Description:
Zinc Sulfate,10mg/ml injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
3

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0480-2019

Code Information:
Lot: 10302018@7, BUD 12/14/2018

Product Description:
Folic Acid, 5mg/ml injection, 10ml vial, Rx Only, Promise Pharmacy Compounding Specialists 31818 US Hwy 19N, Palm Harbor, FL 34684

Product Quantity:
1 10 ml vial

Reason for Recall:
Lack of sterility assurance.

Recall Number:
D-0481-2019

Code Information:
Lot: 10302018@8, BUD 12/14/2018

Class II Drugs Event

Event ID:
81960

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/15/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/14/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Tris Pharma Inc.
2033 US Highway 130
Monmouth Junction NJ United States

Distribution Pattern:
One distributor who further distributed Nationwide in the USA.

Associated Products

Product Description:
Infants' Ibuprofen, Concentrated Ibuprofen Oral Suspension, USP, (NSAID), 50 mg per 1.25 mL, Dye Free, Non-staining Berry Flavor, 0.5 FL OZ (15 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 39338 3, NDC 59779-925-23.

Product Quantity:
46,080 bottles

Reason for Recall:
Superpotent Drug: recalled lots may have higher concentration of ibuprofen than amount labeled.

Recall Number:
D-0493-2019

Code Information:
Lot#: 4718, Exp 12/19

Product Description:
infants* IBUPROFEN, Concentrated Ibuprofen Oral Suspension, USP (NSAID), 50 mg per 1.25 mL, Dye-Free Berry Flavor, 1 FL OZ (30 mL) bottle, Distributed by Wal-Mart Stores, Inc., Bentonville, AR 72716, NDC 49035-125-24.

Product Quantity:
35,328 bottles

Reason for Recall:
Superpotent Drug: recalled lots may have higher concentration of ibuprofen than amount labeled.

Recall Number:
D-0494-2019

Code Information:
Lot#: 00717005A, Exp 02/19

Product Description:
Infants' Ibuprofen, Concentrated Ibuprofen Oral Suspension, USP, (NSAID), 50 mg per 1.25 mL, Dye Free, Non-staining Berry Flavor, 1 FL OZ (30 mL) bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, UPC 0 50428 39961 3, NDC 50428-1252-4.

Product Quantity:
35,280 bottles

Reason for Recall:
Superpotent Drug: recalled lots may have higher concentration of ibuprofen than amount labeled.

Recall Number:
D-0495-2019

Code Information:
Lot#: 00717006A, Exp 02/19

Class II Drugs Event

Event ID:
81982

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/24/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/08/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
US Compounding Inc
1270 Dons Ln
Conway AR United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
LET Gel 4% (Lidocaine HCl 4% + EPINEPHrine HCl 0.05% + Tetracaine HCl 0.5%), 3mL Single Use Syringe, Rx only, US Compounding, 1270 Don's Lane, Conway, AR, 800-718-3588, Barcode 62295501303.

Product Quantity:
1931 syringes

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date: Labels are missing lot and expiration date and are printed as Lot# YYYDDYY@XX with a Beyond Use Date: MM/DD/YYY.

Recall Number:
D-0482-2019

Code Information:
Labeled as Lot# YYYDDYY@XX, Beyond Use Date: MM/DD/YYYY.

Class III Drugs Event

Event ID:
81836

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
12/20/2018

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/08/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Akorn Inc
1925 W Field Ct Ste 300
Lake Forest IL United States

Distribution Pattern:
Nationwide USA and Puerto Rico

Associated Products

Product Description:
COSOPT Ophthalmic Solution, USP, (2% Dorzolamide Hydrochloride, 0.5% Timolol Maleate), 10 mL dropper bottle, Sterile, Rx only, Distributed by: Akorn, Inc., Lake Forest, IL, NDC: 17478-605-10

Product Quantity:
30,794 bottles

Reason for Recall:
Failed Stability Specifications: out of specification results for opalescence at 7 month stability study.

Recall Number:
D-0483-2019

Code Information:
Lots: 426007 and 426008, exp 4/2020

Class III Drugs Event

Event ID:
81914

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/11/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/14/2019

Initial Firm Notification of Consignee or Public:
Two or more of the following: Email, Fax, Letter, Press Release, Telephone, Visit

Recalling Firm:
Oxalis Labs

Lodhimajra Tehsil - Baddi
Theda India

Distribution Pattern:
Product was distributed to 4 major distributors in IL, NY, AR, KY who may have further distribute the product throughout the United States.

Associated Products

Product Description:
Clobetasol Propionate Topical Solution USP, 0.05% w/w, 50 mL bottle, Manufactured for: Macleods Pharma USA, Inc. Plainsboro, NJ 08536 Manufacturer: Macleods Pharmaceuticals Ltd Al Oxalis Labs Baddi Himachal Pradesh INDIA, UPC Code 33342032186 ---- NDC 33342-321-86

Product Quantity:
53,358 bottles

Reason for Recall:
Defective Container; complaints of leakage.

Recall Number:
D-0492-2019

Code Information:
Lot Numbers: PCA801A, PCA802A, PCA803A, exp. date 12/2019; PCA804A, PCA805A, PCA806A, PCA807A, exp. date 04/2020

Class III Drugs Event

Event ID:
82021

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/30/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/14/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Valeant Pharmaceuticals North America LLC
400 Somerset Corporate Blvd
Bridgewater NJ United States

Distribution Pattern:
Nationwide in the USA and Puerto Rico

Associated Products

Product Description:
Cardizem CD (ditiazem HCl) capsules, 120 mg, packaged in a) 30-count bottles (NDC 0187-0795-30); and b) 90-count bottles (NDC 0187-0795-42), Rx Only, Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7, Canada.

Product Quantity:
1023 bottles

Reason for Recall:
Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.

Recall Number:
D-0487-2019

Code Information:
Lots: a) 18J023P, Exp 08/2020; b) 18J021P, Exp 08/2020

Product Description:
Cardizem CD (ditiazem HCl) capsules, 180 mg, packaged in a) 30-count bottles (NDC 0187-0796-30); and b) 90-count bottles (NDC 0187-0796-42), Rx Only, Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7, Canada.

Product Quantity:
206 bottles

Reason for Recall:
Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.

Recall Number:
D-0488-2019

Code Information:
Lots: a) 18J018P, Exp 08/2020; b) 18J029P, Exp 08/2020

Product Description:
Cardizem CD (ditiazem HCl) capsules, 240 mg, packaged in a) 30-count bottles (NDC 0187-0797-30); and b) 90-count bottles (NDC 0187-0797-42), Rx Only, Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7, Canada.

Product Quantity:
390 bottles

Reason for Recall:
Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.

Recall Number:
D-0489-2019

Code Information:
Lots: a) 18J019P, Exp 08/2020; b) 18J028P, Exp 08/2020

Product Description:
Cardizem CD (ditiazem HCl) capsules, 300 mg, packaged in a) 30-count bottles (NDC 0187-0798-30); and b) 90-count bottles (NDC 0187-0798-42), Rx Only, Manufactured for: Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7, Canada.

Product Quantity:
22 bottles

Reason for Recall:
Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.

Recall Number:
D-0490-2019

Code Information:
Lots: a)18J020P, Exp 08/2020; b) 18J034P, Exp 08/2020

Product Description:
Diltiazem HCl CD capsules, 360 mg, 90-count bottles, Rx Only, Manufactured for: Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA; By: Valeant Pharmaceuticals International, Inc., Steinbach, MB R5G 1Z7 Canada; NDC 68682-521-01.

Product Quantity:
23,884 bottles

Reason for Recall:
Failed Dissolution Specifications: high out of specification results for dissolution when measuring the amount of drug released at certain time points.

Recall Number:
D-0491-2019

Code Information:
Lots: 18J035P, 18K094P, 18K093P, Exp 09/2020

Class III Drugs Event

Event ID:
82037

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/01/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:
02/08/2019

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Lupin Pharmaceuticals Inc.
111 S Calvert St Fl 21ST
Baltimore MD United States

Distribution Pattern:
Product was distributed by 5 wholesalers, 6 drug chains, 4 mail order pharmacies and 1 mail order pharmacy/supermarket who may have further distribute the product throughout the United States.

Associated Products

Product Description:
Moxifloxacin Ophthalmic Solution USP, 0.5%, 3 mL dropper bottle, Rx Only, Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 Manufactured by: lupin Limited Pithampur (M.P.) 454 775 India. NDC 68180-422-01

Product Quantity:
43,860 3ml bottles

Reason for Recall:
Failed Impurities/Degradation Specifications: Out of specification test results in related substance at three-month long term stability study was obtained.

Recall Number:
D-0484-2019

Code Information:
Lot Numbers: H705562, H705563, EXP. 11/2019; H800616, EXP. 01/2020

Not Yet Classified Drugs Event

Event ID:
82065

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/06/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Distributed Nationwide in the USA

Associated Products

Product Description:
Esomeprazole Magnesium Delayed-Release Capsules USP, 40mg*, 90-count bottle, Rx only, Mfd By: Dr. Reddy's Laboratories Limited BAchupally - 500 090 INDIA. NDC 43598-510-90

Product Quantity:
20,784 90 count bottles

Reason for Recall:
Discoloration: Esomeprazole Magnesium DR Capsules (40mg) may contain brown pellets.

Recall Number:

Code Information:
Lot # C800589, Exp 5/2019

Not Yet Classified Drugs Event

Event ID:
82102

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/08/2019

Voluntary / Mandated:
Voluntary: Firm Initiated

Center Classification Date:

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Avella of Deer Valley, Inc. Store 38
24416 N 19th Ave
Phoenix AZ United States

Distribution Pattern:
Distribution to 13 states: Alabama, Arizona, California, Colorado, Florida, Idaho, Michigan, Minnesota, North Carolina, New Jersey, Oregon, Pennsylvania, Texas.

Associated Products

Product Description:
Labetalol 20mg, HCL, USP Injectable Solution, 20mg/4mL (5 mg per mL), 4mL single use syringe. Repackaged by Avella Specialty Pharmacy 24416 N 19th Avenue, Phoenix, AZ 85085 (877) 794-0404, NDC 42852-822-71.

Product Quantity:
2,840 4mL syringes

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date:The product labels contain a Two-Dimensional (2D) barcode that, when scanned, reveals information specific to the batch of the labeled product, including Expiration Date. The expiration date included within these 2D barcodes is incorrect and does not match the correct expiration date listed on the face of the label itself.

Recall Number:

Code Information:
138-20182712@49, BUD 4/6/2019; 138-20182712@63, BUD 4/6/2019; 138-20182712@89, BUD 4/6/2019; 138-20182712@90, BUD 4/6/2019; 138-20182712@93, BUD 4/6/2019; 138-20183112@88, BUD 4/10/2019; 138-20183112@89, BUD 4/10/2019;138-20183112@91, BUD 4/10/2019; 138-20190201@96, BUD 4/12/2019

Product Description:
MAGnesium 1gm sulfate, added to D5W 50 mL, Volume 52 mL, sterile single use bag, Compounded by Avella Specialty Pharmacy 24416 N 19th Avenue, Phoenix, AZ 85085 (877) 794-0404, NDC 42852-901-05.

Product Quantity:
250 52 mL bags

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date:The product labels contain a Two-Dimensional (2D) barcode that, when scanned, reveals information specific to the batch of the labeled product, including Expiration Date. The expiration date included within these 2D barcodes is incorrect and does not match the correct expiration date listed on the face of the label itself.

Recall Number:

Code Information:
Lot number: 138-20182409@31, BUD 12/23/2018

Product Description:
MAGnesium 2gm sulfate, added to D5W 50 mL, Volume: 54 mL, Sterile single use bag, Compounded by Avella Specialty Pharmacy 24416 N 19th Avenue, Phoenix, AZ 85085 (877) 794-0404, NDC 42852-902-05.

Product Quantity:
4,950 54 mL bags

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date:The product labels contain a Two-Dimensional (2D) barcode that, when scanned, reveals information specific to the batch of the labeled product, including Expiration Date. The expiration date included within these 2D barcodes is incorrect and does not match the correct expiration date listed on the face of the label itself.

Recall Number:

Code Information:
138-20182509@110, 138-20182509@111; 138-20182509@112, BUD 12/24/2018; 138-20180210@76, 138-20180210@86, BUD 12/31/2018; 138-20180410@66, BUD 1/2/2019; 138-20183110@43, 138-20183110@44, BUD 1/29/2019; 138-20180111@84, 138-20180111@85, BUD 1/30/2019; 138-20180611@36, 138-20180611@39, 138-20180611@52, 138-20180611@60, BUD 2/4/2019; 138-20181911@125; 138-20181911@126, BUD 2/17/2019; 138-20182011@56, BUD 2/18/2019.

Product Description:
MAGnesium 2 gm sulfate, added to NS 50 mL, Sterile single use bag, 54 mL, Compounded by Avella Specialty Pharmacy 24416 N 19 th Avenue, Phoenix, AZ 85085 (877) 794-0404, NDC 42852-907-05.

Product Quantity:
8,500 54 mL bags

Reason for Recall:
Labeling: Incorrect or Missing Lot and/or Exp Date:The product labels contain a Two-Dimensional (2D) barcode that, when scanned, reveals information specific to the batch of the labeled product, including Expiration Date. The expiration date included within these 2D barcodes is incorrect and does not match the correct expiration date listed on the face of the label itself.

Recall Number:

Code Information:
138-20181909@53, BUD 12/18/2018; 138-20182009@10, 138-20182009@2, 138-20182009@3, 138-20182009@4, 138-20182009@5, 138-20182009@6, 138-20182009@7, 138-20182009@8, 138-20182009@9, BUD 12/19/2018; 138-20182109@35, BUD 12/20/2018; 138-20180410@54, BUD 1/2/2019; 138-20180510@107, 138-20180510@108, 138-20180510@92, BUD 1/3/2019; 138-20182210@97, BUD 1/20/2019; 138-20181212@103, BUD 3/12/2019.